JUN 2 1 2004 K040135 1/3

13.0 510(k) Safety Summary

A. Name of Device

Trade Name: Thermage ThermaCool System

Common Name: Electrosurgical Unit and Accessories

Classification Name: Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)

Contact Person: Pamela M. Buckman, RN, MS
Vice President, Regulatory/Clinical Affairs

B. Predicate Device

ThermaCool System

510 (k) Number	Name of Device	Decision Date
K021402	ThermaCool TC	November 5, 2002

C. Device Description

The Thermage ThermaCool System consists of the following components:

- RF Generator
- Cooling Module
- Cryogen Canister
- Handpiece Assembly (consisting of Handpiece and Treatment Tip)
- Accessory cables and tubing
- Optional footswitch component
- Accessories: coupling fluid, return pad and skin marking paper

The Handpiece Assembly and Cooling Module connect to the RF Generator.

D. Indicated Use

The Thermage ThermaCool System is indicated for use in Dermatologic and General Surgical procedures for electro coagulation and hemostasis; non-invasive treatment of periorbital wrinkles and rhytids and non-invasive treatment of facial wrinkles and rhytids.

There is a sterilization contract in compliance with 21 CFR 801.150 between Thermage and IBA Griffith. This contract defines the responsibilities of both parties. Sterilization validation will be performed in accordance with EN 550, utilizing the half-cycle method of sterilization validation to verify a sterility assurance level of 10^{-6}.

EO Residuals

Acceptable EO residual levels will be in conformance with the requirements of consensus standard ISO 10993-7: Biological Evaluation of Medical Devices Part 7 Ethylene Oxide Sterilization Residuals. The Thermage Treatment Tip is a "limited exposure" device in accordance with ISO 10993-1:1992, subclause 5.2 (limited exposure: devices whose single or multiple use or contact is likely to be up to 24 hours). Allowable limits for limited exposure devices are: 20 mg EO and 12 mg ECH (average daily dose).

Verification that EO and ECH residuals are below allowable limits shall be confirmed as part of the EO cycle and product aeration validation. Manufactured product shall also be routinely monitored for EO and ECH residuals (minimum quarterly).

Skin Marking Paper

Sterilization

The Thermage Skin Marking Paper will be sterilized using 100% ethylene oxide at IBA Griffith in Salt Lake City, Utah. The address is 5725 West Harold Gatty Road, Salt Lake City, Utah 84116. The establishment registration number is 1721676.

There is a sterilization contract in compliance with 21 CFR 801.150 between Thermage and IBA Griffith. This contract defines the responsibilities of both parties. Sterilization validation will be performed in accordance with EN 550, utilizing the half-cycle method of sterilization validation to verify a sterility assurance level of 10^{-6}.

EO Residuals

Acceptable EO residual levels will be in conformance with the requirements of consensus standard ISO 10993-7: Biological Evaluation of Medical Devices Part 7 Ethylene Oxide Sterilization Residuals. The Thermage Skin Marking Paper is a "limited exposure" device in accordance with ISO 10993-1:1992, subclause 5.2 (limited exposure: devices whose single or multiple use or contact is likely to be up to 24 hours). Allowable limits for limited exposure devices are: 20 mg EO and 12 mg ECH (average daily dose).

Verification that EO and ECH residuals are below allowable limits shall be confirmed as part of the EO cycle and product aeration validation. Manufactured product shall also be routinely monitored for EO and ECH residuals (minimum quarterly).

K040135 3/3

E. Technical characteristics

The technological characteristics and clinical use data of the ThermaCool System for the expanded indication are substantially equivalent to the previously cleared ThermaCool TC System.

F. Summary

By virtue of design, principle of operation, materials and intended use, the Thermage ThermaCool System is substantially equivalent to devices currently cleared for marketing in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 1 2004

Ms. Pamela M. Buckman, RN, MS
Vice President, Regulatory/Clinical Affairs
Thermage
4058 Point Eden Way
Hayward, California 94545-3721

Re: K040135
Trade/Device Name: Thermage ThermaCool System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 30, 2004
Received: May 3, 2004

Dear Ms. Buckman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): Not Known K040135

DEVICE NAME: Thermage ThermaCool System

INDICATIONS FOR USE:

The Thermage ThermaCool System is indicated for use in:

- Dermatologic and general surgical procedures for electro coagulation and hemostasis,
- Non-invasive treatment of periorbital wrinkles and rhytids
- Non-invasive treatment of facial wrinkles and rhytids

Prescription Use	X	OR	Over-The-Counter-Use	

(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040135